

510(k) Summary (Summary of Safety and Effectiveness)

K103627

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

OCT 14 2011

Applicant Name:

Judith Wallach, Regulatory Affairs Administrator

Regulatory Affairs

Abbott Laboratories Diagnostics Division

Dept. 9V6, AP6C-2

100 Abbott Park Road

Abbott Park, IL 60064

Phone and fax numbers 847-937-1132, FAX 847-937-4836

Date prepared October 12, 2011

Device Name:

Reagent Kit

Classification Name: Carbamazepine test system

Trade Name: ARCHITECT iCarbamazepine

Common Name: Carbamazepine

Governing Regulation: 862.3645

Device Classification: Class II

Classification Panel: Clinical Toxicology

Code: KLT

ARCHITECT iCarbamazepine Calibrator Kit

Classification Name: Calibrators, Drug Specific

Trade Name: ARCHITECT iCarbamazepine

Common Name: Calibrator

Governing Regulation: 862.3200

Device Classification: Class II

Classification Panel: Clinical Toxicology

Code: DLJ

Legally marketed device to which equivalency is claimed:

AxSYM Carbamazepine (K935374)

Intended Use of the Device

The ARCHITECT *i*Carbamazepine assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of carbamazepine, an anticonvulsant drug, in human serum or plasma (collected in lithium heparin, sodium heparin, dipotassium EDTA or sodium EDTA tubes) on the ARCHITECT *i* System with *STAT* protocol capability. The measurements obtained are used in monitoring levels of carbamazepine to help ensure appropriate therapy.

Description of Device

The ARCHITECT *i*Carbamazepine assay is a one-step immunoassay for the quantitative measurement of carbamazepine in human serum or plasma using CMIA technology with flexible assay protocols referred to as Chemiflex.

In the ARCHITECT *i*Carbamazepine assay, sample, anti-carbamazepine coated paramagnetic microparticles, and carbamazepine acridinium-labeled conjugate are combined to create a reaction mixture. The anti-carbamazepine coated microparticles bind to carbamazepine present in the sample and the carbamazepine acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of carbamazepine in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Comparison of Technological Characteristics:

The ARCHITECT *i*Carbamazepine assay utilizes chemiluminescent microparticle immunoassay (CMIA) technology for the quantitative measurement of carbamazepine, an anticonvulsant drug, in human serum or plasma. The AxSYM Carbamazepine assay utilizes Fluorescence Polarization Immunoassay (FPIA) technology for the quantitative measurement of carbamazepine, an anticonvulsant drug, in serum or plasma.

Summary of Analytical Performance:

The ARCHITECT *i*Carbamazepine assay is substantially equivalent to the AxSYM Carbamazepine assay in terms of analytical performance data in this 510(k) submission.

The analytical performance of the ARCHITECT iCarbamazepine assay was demonstrated through the following studies, which are provided in this 510(k) submission:

- Precision
- Sensitivity (Limit of Blank, Limit of Detection, and Limit of Quantitation)
- Linearity
- Interferences
- Recovery
- Manual Dilution
- Matrix Comparison (Tube Type)
- Method Comparison (Correlation)



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Laboratories
c/o Ms. Judith Wallach
Regulatory Affairs Administrator
Dept. 9V6, AP6C-2
100 Abbott Park Road
Abbott Park, IL 60064

OCT 14 2011

Re: k103627

Trade/Device Name: Architect /Carbamazepine Immunoassay
Regulation Number: 21 CFR 862.3645
Regulation Name: Carbamazepine test system
Regulatory Class: Class II
Product Code: KLT, DKB
Dated: October 12, 2011
Received: October 13, 2011

Dear Ms. Wallach

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

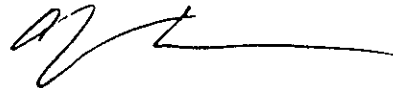
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K 103627

Device Name: ARCHITECT iCarbamazepine

Indications for Use:

Reagents:

The ARCHITECT iCarbamazepine assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of carbamazepine, an anticonvulsant drug, in human serum or plasma (collected in lithium heparin, sodium heparin, dipotassium EDTA or sodium EDTA tubes) on the ARCHITECT i System with STAT protocol capability. The measurements obtained are used in monitoring levels of carbamazepine to help ensure appropriate therapy.

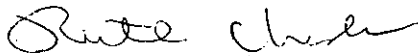
Calibrators:

The ARCHITECT iCarbamazepine Calibrators are for the calibration of the ARCHITECT i System with STAT protocol capability when used for the quantitative measurement of carbamazepine, an anticonvulsant drug, in human serum or plasma.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 103627